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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,463	07/26/1999	DAVID WYNICK	23016.0002	4323

23859 7590 03/10/2005

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ATLANTA, GA 30309-3915

EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/230,463

Applicant(s)

WYNICK, DAVID

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. First, there is no literal support for the newly added negative limitation of claim 18, "wherein the subject is not a rat" in the specification as filed. Second, the specification does not list alternative elements in a positive recitation, which MPEP 2173.05(i) requires as a possible basis in order for an alternative element to be explicitly excluded in the claims. In support of the Examiner's position, see the instant specification concerning the instant claims at page 3, lines 1-3; page 12, lines 5-11; and page 13, lines 9-13. These are the only portions of the specification that support the instant claims, and they are silent in regards to alternative elements positively recited so that they may be explicitly excluded. Third, the findings of

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In re Johnson, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977) are not applicable to the instant Application, as the fact pattern of the instant Application deviates from *Johnson* in significant and notable ways. *In re Johnson*, the court concluded that there was "ample basis" for claims drawn to a "limited genus," even if the limited genus lacked antecedent basis. In contrast, in the instant Application, Applicant has failed to establish **any** basis for claims drawn to a limited genus, other than referring to the holdings of *In re Johnson*. The *Johnson* case was drawn mostly to chemical compound (product) claims, where many different species (dozens) were identified and described. The instant Application is not a chemical product case, and dozens of different species or embodiments of the instant claims are sorely lacking from the instant disclosure. The instant disclosure, therefore, does not provide an ample basis for the newly amended claims drawn to a limited genus.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors.

5. Claims 18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luo et al. ("Luo") in view of Zhang et al. ("Zhang"). Luo describes methods where galanin is administered to treat spinal cord hyperexcitability following sciatic nerve section which is peripheral nerve damage (abstract and pages 162-163). Luo does not teach that his method is applicable to subjects that are not rats. Zhang discloses that

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the findings in rat concerning galanin and peripheral nerve damage are valid and applicable in primates as well.

"The main reason underlying our experiments was to explore whether the peptide galanin is upregulated in primates as it is in rats, since we have proposed that galanin may represent an endogenous analgesics compound activated after peripheral nerve lesions. Consequently, galanin agonists should represent new pharmacological tools to suppress chronic pain. The present findings show that, since some of these mechanisms also operate in monkey, this hypothesis is valid also for primates and provide a further impetus to test galanin or galanin agonists in humans" (page 375 of Zhang).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use galanin as a treatment following peripheral nerve damage as taught by Luo in primates, including humans, as taught by Zhang, for therapeutic purposes, including the treatment of peripheral nerve damage and pain resulting from such.

Applicant's arguments and declaration filed 7/1/04 have been fully considered but they are not persuasive because the arguments and declaration are drawn to limitations not recited in the claims. The claims are not limited to peripheral administration of galanin, nor do the claim limitations exclude the use of galanin to treat peripheral nerve damage that concomitantly produces neuropathic pain. Furthermore, there are no limitations in the claims as to what comprises "nerve regeneration" while Applicant's arguments and declaration are drawn to observable, complete and full regeneration. Nerve regeneration as recited in the instant claims encompasses the preliminary beginnings of regeneration up to and including its full completion and expression, and nothing persuasive is provided by Applicant's arguments or declaration that nerve regeneration does not begin within a few minutes or hours of administering galanin, absent any evidence of record to the contrary.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

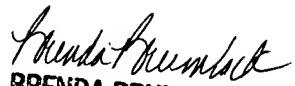
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supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (571)-273-8300.



Stephen Gucker

March 7, 2005



BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600